

§ 1309.63

21 CFR Ch. II (4–1–06 Edition)

§ 1309.63 Transfer of registration.

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administrator may specifically designate and then only pursuant to his written consent.

SECURITY REQUIREMENTS

§ 1309.71 General security requirements.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of List I chemicals. Specific attention shall be paid to storage of and controlling access to List I chemicals as follows:

(1) Chemicals shall be stored in containers sealed in such a manner as to indicate any attempts at tampering with the container. Where chemicals cannot be stored in sealed containers, access to the chemicals should be controlled through physical means or through human or electronic monitoring.

(2) In retail settings open to the public where drugs containing ephedrine as the sole active medicinal ingredient are distributed, such drugs will be stocked behind a counter where only employees have access.

(b) In evaluating the effectiveness of security controls and procedures, the Administrator shall consider the following factors:

(1) The type, form, and quantity of List I chemicals handled;

(2) The location of the premises and the relationship such location bears on the security needs;

(3) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(4) The availability of electronic detection and alarm systems;

(5) the extent of unsupervised public access to the facility;

(6) The adequacy of supervision over employees having access to List I chemicals;

(7) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel in areas where List I chemicals are processed or stored;

(8) The adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List I chemicals in its operations.

(c) Any registrant or applicant desiring to determine whether a proposed system of security controls and procedures is adequate may submit materials and plans regarding the proposed security controls and procedures either to the Special Agent in Charge in the region in which the security controls and procedures will be used, or to the Chemical Operations Section Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537.

[60 FR 32454, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997; 67 FR 14861, Mar. 28, 2002]

§ 1309.72 Felony conviction; employer responsibilities.

(a) The registrant shall exercise caution in the consideration of employment of persons who will have access to listed chemicals, who have been convicted of a felony offense relating to controlled substances or listed chemicals, or who have, at any time, had an application for registration with the DEA denied, had a DEA registration revoked, or surrendered a DEA registration for cause. (For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any Federal or State administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances or listed chemicals.) The registrant should be aware of the circumstances regarding the action against the potential employee and the rehabilitative efforts following the action. The registrant shall assess the risks involved in employing such persons, including the potential for action against the registrant pursuant to § 1309.43. If such person is found to have diverted listed chemicals, and, in the event of employment, shall institute procedures to limit the potential for diversion of List I chemicals.

(b) It is the position of DEA that employees who possess, sell, use or divert listed chemicals or controlled substances will subject themselves not

Drug Enforcement Administration, Justice

§ 1310.02

only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

§ 1309.73 Employee responsibility to report diversion.

Reports of listed chemical diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of chemical diversion will be considered in determining the feasibility of continuing to allow an employee to work in an area with access to chemicals. The employer shall inform all employees concerning this policy.

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

Sec.

- 1310.01 Definitions.
- 1310.02 Substances covered.
- 1310.03 Persons required to keep records and file reports.
- 1310.04 Maintenance of records.
- 1310.05 Reports.
- 1310.06 Content of records and reports.
- 1310.07 Proof of identity.
- 1310.08 Excluded transactions.
- 1310.09 Temporary exemption from registration.
- 1310.10 Removal of the exemption of drugs distributed under the Food, Drug and Cosmetic Act.
- 1310.11 Reinstatement of exemption for drug products distributed under the Food, Drug and Cosmetic Act.

1310.12 Exempt chemical mixtures.

1310.13 Exemption of chemical mixtures; application.

1310.14 Exemption of drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

1310.21 Sale by Federal departments or agencies of chemicals which could be used to manufacture controlled substances.

AUTHORITY: 21 U.S.C. 802, 827(h), 830, 871(b) 890.

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

§ 1310.01 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1310.02 Substances covered.

The following chemicals have been specifically designated by the Administrator of the Drug Enforcement Administration as the listed chemicals subject to the provisions of this part and parts 1309 and 1313 of this chapter. Each chemical has been assigned the DEA Chemical Code Number set forth opposite it.

(a) List I chemicals

- (1) Anthranilic acid, its esters, and its salts8530
- (2) Benzyl cyanide.....8735
- (3) Ephedrine, its salts, optical isomers, and salts of optical isomers8113
- (4) Ergonovine and its salts8675
- (5) Ergotamine and its salts.....8676
- (6) N-Acetylanthranilic acid, its esters, and its salts.....8522
- (7) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers8317
- (8) Phenylacetic acid, its esters, and its salts.....8791
- (9) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers1225
- (10) Piperidine and its salts2704
- (11) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.....8112
- (12) 3,4-Methylenedioxyphe-
nyl-2-propanone8502